EPA Comment Number: 550-100

Received: February 13, 2000

To: Homepage Oppts/DC/USEPA/US@EPA

cc:

Subject: Docket #OPP-00550 - Comment letter on Draft of Preliminary Food Safety Strategic Plan

I am enrolled in an Administrative Law class at Georgia State University College of Law. One assignment was to submit a comment letter, which is why the attached letter is entitled "admin law comment," however, this document does pertain to the above referenced subject. Thank you.

- att1.htm
- Admin law comment letter.doc

Attachment

LORI BROWNE 1416 A Druid Valley Drive Atlanta, GA 30329

February 13, 2000

Food and Drug Administration Dockets Management Branch

RE: Docket #97N-0074

General E-Mail Docket #OPP-00550

President's Council on Food Safety

Call for Comments on the Draft of Preliminary Food Safety Strategic Plan

Dear Sir/Madam:

I am currently a second year, part-time evening student at the Georgia State University College of Law. This is in response to the request for comments regarding the Draft of the Preliminary Food Safety Strategic Plan for Public Review developed in accordance with the establishment of the President's Council on Food Safety. I would like to take this opportunity to address the general/crosscutting questions and the questions pertaining to each goal you have asked the public to comment on. I have had an opportunity to review the draft, along with the 102 page transcript of the meeting held in Washington on January 19, 2000 and wish to submit this comment letter for your consideration. After reading the plan draft and the transcript of the public meeting, I am highly in agreement with many of the specific concerns addressed by the people who were in attendance.

I have also read a variety of other sources in order to present a more comprehensive response to your agency's inquiry. For instance, I must say that I was very disturbed to find out that according to the Vol. 5, No. 5 September-October issue of the Center for Disease Control's issue reporting on Emerging Infectious Diseases, more than 200 known diseases are transmitted through food and that in the United States, foodborne diseases have been estimated to cause 6 million to 81 million illnesses and up to 9,000 deaths each year; and the United States has one of the safest food supplies in the world according to your comment request notification? I find these statistics frightening and the numbers present unacceptable losses to be incurred through a basic human necessity of life.

Even in the process of my research and investigation on this topic, within the one week period prior to my submission of this letter, my co-worker informed me of an incident of a recall of Hi-C drink mix, which her daughter had been drinking and was suffering from a stomach illness prior to the recall, in addition to reports of more than 100 or so people becoming violently ill and nauseated after eating cakes purchased from Publix Supermarkets here in the Atlanta area. I fully agree that immediate steps need to be taken to address these problems and make the food that we consume and the water we are exposed to and drink even safer.

Overall, the overarching goal and framework of the plan are fairly well-focused and comprehensive, at least as a starting point of where to go. This is a good step towards assessing and narrowing down the best way to deal with the food and water safety issue. I think that the emphasis does need to be placed on prevention and education at all levels first. Also, establishing time frames for implementation of various stages of the plan would be a good idea to add to the "overarching goal" section, i.e., "the United States food safety system is dedicated to minimizing the illnesses and deaths that occur yearly to at least half of that of the year 1999 by the year 2005," etc. I believe that the addition of specific time frames would present the appearance of a serious and concerted effort by the government to assure the safety of the nation's food and water supplies.

With regards to the sound science goal, adding language to the effect of the government, "engaging in active recruitment of qualified, trained, certified personnel who will research, inspect, and regulate food safety and advance the overall goals of the plan," may be worthwhile. In addition, possibly adding some type of objective to implement incentives and/or educational funding to encourage and provide opportunities for individuals to enter into health sciences and food safety related career fields at the college level.

With regards to risk assessment, providing for the encouragement of workers in the food industry to monitor themselves and report violations without fear of retribution could prove to be an invaluable aid to the assessment of risks and further aid in the advancement of food safety.

The communication goal needs to be well thought out, especially on how to best report potential risks to the public by utilizing all the media available and at the same time assuring that the information is as accurate as possible and reaches the maximum amount of people at risk. For instance, reporting risks over the Internet could be an effective way of more people getting access to information, however, there is probably a need to figure out how to dispense information

without the public thinking it may be an Internet hoax.

As an example, during the same week of my submission of this letter, I received an e-mail which was forwarded to me by a friend which stated that several shipments of bananas received here in the United States from Costa Rica were infected with the flesh eating bacteria. It further went on to say that the FDA was reluctant to issue a country wide warning because of fear of a nationwide panic. Of course, the originator of this e-mail stated that he "checked the source and it was validated from the CDC."

Furthermore, somewhere in the strategic plan and/or the transcript, an occurrence of an outbreak was mentioned, but it was stated that the level of communication to the public did not take place. It seems a better alternative to release information, even on minor matters, to instill the public confidence in either the existing agencies or any new agency which may be established. It may be better to generate a small amount of fear in the general public, then to let any number of people become ill or die unnecessarily. Maybe some type of mass e-mailing that is encoded with the appropriate agency logo that only it can issue. I point this out to say that the plan needs to address ways in which to make sure that the public takes any reported risks seriously, whether through the Internet, television, radio, newspapers or billboards.

Mitigating the existence of duplicative efforts across agency lines, promoting maximum efficiency and minimizing the requirement of bureaucratic red-tape in the event of an outbreak emergency should be given priority. While reading the hearing transcript, I detected a high level of frustration from many of the speakers who were representing various state health agencies and food industries. A running theme was the concern that there is a lot of over-lap in the numerous agencies' functions. When more than one agency is potentially responsible for the same function(s), what I see happening is a type of "pass-the-buck" mentality because one agency will put off the responsibility onto another agency and it will go back and forth and no action takes place. This is where things slip through the cracks and more people could become seriously ill, or possibly die, as a result.

For example, their were two gentlemen in the food industry who relayed their first-hand frustrations with the bureaucratic red tape, although they were actively trying to process food correctly and comply with regulations. One gentleman said something along the lines of his company waiting on an approval letter regarding their radiation practices, they never heard anything, and when they made an inquiry to the government of when they could get a response, they got a circular argument that because the government did not do "small paper requests/issuances anymore" they would not get a response. The other story was about how one agency passed the buck to another agency regarding food inspection of the company's product because it was not within the realm of their responsibilities. Tightening and eliminating the gaps in responsibilities and duties in the system will help advance the overall goals of the plan.

My expectation of success is significant, but realistic. Obviously the government has taken the first step in acknowledging that things can be better. However, things will need to be worked out and corrections made as the plan is implemented. An obvious way to measure success is to assess the number of illnesses and outbreaks that occur each year. Another way would be to periodically

survey various food production companies and health agencies to get feedback on how well the system is working for them and where gaps may still exist. This needs to be a continuing process.

As one of the speakers at the hearing aptly commented, 'laws can be changed." Another speaker thought that it was time to have an independent person evaluate the current system and take an objective look at where the gaps exist and duties overlap. This may be a good idea to expedite the process by having some outside, objective, individual assess the system.

The strategic plan also posses several different options regarding the best way to go about agency structure towards implementation of the plan, i.e., whether to tailor and condense the responsibilities of existing agencies or create an entirely new one to deal with food safety. In evaluating what steps may be taken to eliminate gaps and improve efficiency, I had an opportunity to read over the enabling acts for the EPA and the Food and Drug Administration.

As I read over the enabling act for the Food and Drug Administration, there was noted within that act pending legislation specifically addressing the nation's food safety issue. The legislation was introduced to the House on April 28, 1999 (H.R. 1612). It vested and streamlined many responsibilities to the Food and Drug Administration and I thought much of the proposed legislation made sense. It addressed many of the issues discussed in the plan and at the meeting, from how to coordinate and implement the program on the federal, national and international levels, proposed time lines, provided for education of all individuals in the "farm to table" continuum, in addition to assessing penalties for non-compliance and a "whistleblower protection" provision. If it has not already been one of the legislative materials under your review, I believe reviewing this bill may be highly worthwhile.

It seems that it would be more expeditious to streamline the current responsibilities already vested in the existing agencies and maybe transfer more of the direct food consumption related responsibilities to the Food and Drug Administration, as it seems that this is the agency that would have the broadest scope in this regard. After reviewing the enabling acts, in addition to the comments contained within the plan and the hearing transcript regarding the authority of different agencies, it appears that the authoritative structures are in place to advance the plan goals; it is just a matter of re-organization and possible re-distribution of authority. It seems this would save time and money. However, the cooperative effort with the other federal, local and state agencies in making food and water safe from farm to table, also needs to be emphasized. No matter at what level, the "right had needs to know what the left hand is doing."

In conclusion, whatever the final plan is that ends up being presented to the President's Council on Food Safety in July 2000, I would strongly encourage that all resources available are seriously considered in development of the plan. Most especially, the statements made at the January 19, 2000 hearing should be taken into serious consideration. I thought that the comments made were very enlightening and invaluable since they came from people who have first hand knowledge of food production and health hazard issues and/or have been affected in some way by foodborne related illnesses and felt that the issue was important enough to attend the meeting and voice their concerns and opinions.

I commend you on your attention and efforts and	d sincerely hope that the plan will be as successful
as it has the potential for becoming.	

Thank you.

Sincerely, Lori Browne